K053026

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9. Certification
9.1 Summary for public disclosure

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Date summary prepared:	January 11 , 2005
Device trade name:	KOWA nonmyd 7 (Type F) KOWA nonmyd α -D (Type D)
Classification name:	CAMERA, OPTHALMIC, AC-POWERED
Product code:	HKI

Intended use:

The KOWA nonmyd series, non-mydriatic fundus camera, are intended for use with retina image capturing. The retina image can be stored to an external hard disk drive or transferred in other formats through memory card or serial interface depending on the output interface available for each device.

Device description:

KOWA nonmyd series of camera consist of non-mydriatic fundus cameras with a digital image capture system, which does not require 35mm film or instant film. It maintains the same functionalities of the previous fundus cameras, and by capturing digital images it eliminates film development time, allowing the user to view images immediately.

The KOWA nonmyd series cameras are all fundamentally the same noting exception only to their output interfaces. Type D (KOWA nonmyd α-D) contains an internal CCD camera and exports data via USB interface. Type F (KOWA nonmyd 7) requires a CCD camera to be attached to the device and exports data by both memory card and via USB.

Application software for the KOWA nonmyd series contain a filing system, which can save, display, and manage the digital images.

For detailed observation, the KOWA nonmyd series have an optical variable power feature, which enables the viewer to select a picture angle. By selecting a picture angle it can achieve the same amount of image clarity as a conventional fundus camera.

In addition, the KOWA nonmyd series can be used even in cases where the pupil has not been completely dilated; in addition to the normal pupil diameter 4mm mode, there is also a small pupil diameter 3.7mm mode.

Similar to previous fundus cameras, the KOWA nonmyd series uses infrared light for illumination during alignment to provide a better patient experience. In addition, the devices are equipped with a highly sensitive CCD camera, and are therefore able to capture images at a much lower flash light intensity level than previous fundus cameras, further enhancing the patient experience.

Comparison:

The Nidek NM-1000 was chosen as a substantially equivalent device. The predicate device is a non-mydriatic fundus camera and it is equipped with a high resolution CCD camera so it does not require any film and can display images immediately after image capture. Also because it uses a highly sensitive CCD camera, the flash required for filming is reduced compared to conventional fundus cameras.

Similar to the predicate device, the KOWA nonmyd series cameras are equipped with a highly sensitive CCD so they do not require film and can display images immediately after image capture.

The KOWA nonmyd series, KOWA nonmyd 7 and KOWA nonmyd α-D, and the predicate device also share similar technical and safety characteristics. The result is show in the table below.

Performance testing:

KOWA nonmyd series, KOWA nonmyd 7 and KOWA nonmyd α-D, were tested to the following standards and conform to all specific requirements based on these standards. KOWA nonmyd series are equivalent to the predicate device.

Electrical safety

KOWA nonmyd series were tested in accordance with IEC60601-1: 1988, Amendment 1:1991 and Amendment 2: 1995, and met all requirements of standards.

Electromagnetic compatibility

KOWA nonmyd series were tested in accordance with IEC60601-1-2: 2001, and met all requirements of standard.

Test requirements and test procedure for ophthalmic instruments

KOWA nonmyd series was tested in accordance with ISO15004: 1997, and met all requirements of the standard. Refer to Appendix B for details.

Risk management

KOWA nonmyd series were evaluated in accordance with ISO14971: 2000. The risk management of the devices was deemed satisfactory. Remaining risks will be noted in the user manual, so users will be able to avoid them.

Conclusion:

The KOWA nonmyd series is equipped with the same fundamental technology as the predicate device and maintains the same level of safety performance. Therefore it has been concluded that there are no significant differences in the technical characteristics and safety between KOWA nonmyd series and the predicate device.

Table A: Predicate device

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Nidek Non-Mydriatic Fundus Camera Model NM-1000	Nidek Incorporated	K014274	Apr. 17, 2002

Table B: Predicate Device Comparison

	KOWA nonmyd series: Non-mydriatic fundus camera, type D and F	Nidek Non-mydriatic Fundus Camera Model NM-1000
Intended use	The KOWA nonmyd series, non-mydriatic fundus cameras are intended for use with retina image capturing.	The Nidek NM-1000 is an ophthalmic camera that is intended for use in capturing images of the retina and the anterior segment of the eye.
Saved Image Format	BMP, JPEG	Nidek format, TIF
Picture angle	45degree/20degree	45degree
Working distance	30mm	43.3mm (from camera body to corner)
Working distance detection method	Anterio (Observation) Fundus (Focusing on blight spots)	Anterio (Observation) Fundus (Focusing on blight spots)
Minimum diameter of pupil	Normal pupil mode: 4mm Small pupil mode: 3.7mm	4mm
CCD camera for observation	1/3 inch CCD Camera	1/3 inch CCD Camera
CCD camera for Photographing	Type D: 1/2inch 2.1mega pixel CCD Camera Digital Progressive Scan (built-in) Type F: APS-C size 6mega pixel CCD Camera Digital Progressive Scan (K9L-BM39 used as Digital camera)	1/2inch CCD Camera Digital Progressive Scan (built-in)
Observation Display (B/W)	5.6 inch LCD Monitor	6.4 inch LCD Monitor
Photographing Display	Type D, F: Outer Monitor Use	6.4 inch LCD Monitor
Dioptric compensation	Total -33D to +40D	Total -32D to +40D
Focusing	Split luminous bars coincidence	Manual (motor driven) Split line focus on the retina (-10 to +14D)

Table C: Predicate Device Comparison

	KOWA nonmyd series: Non-mydriatic fundus camera, Type D and F	Nidek Non-mydriatic Fundus Camera Model NM-1000
Observation Light Source	Halogen lamp (Max 12V 100W) with infrared filter	Halogen lamp (Max 12V 50W) with infrared filter
Photographing Light Source	Xenon flash (Max 50WS)	Xenon flash (Max. 25WS)
Internal Fixation Navigation	Fixed fixator selecting	Manual lever
Switching light path of observation & photographing	Same pathway, no beam split	Beam Splitter
Observation light adjustment	Volume adjustment style	Volume adjustment style
Photographing light adjustment	Step adjustment style (5 steps)	Step adjustment style (8 steps)
Camera stand (Base)		
Type	Tabletop; power source built-in	Tabletop; power source built-in
Horizontal Movement	Forward/Backward: 40mm Leftward/Rightward: 100mm	Forward/Backward: 65mm Leftward/Rightward: 106mm
Vertical Movement	30mm	30mm
Shutter Release	Joystick upper button	Joystick upper button
Signal outlet	Type D: USB Type F: Flash memory card	USB, RGB Analog, NTSC Composite Video
Chinrest		
Vertical Movement of chinrest	60mm	65mm
External Fixation Targets	Free-arm style (Option)	Free-arm style (Option)
Compliance with safety standards		
Safety requirements	IEC60601-1	EN60601-1
EMC	IEC60601-1-2	EN60601-1-2
Ophthalmic instrument requirements	ISO15004	ISO15004
Dimensions		
Size	Type F: 310mm(W) x 504mm(D) x 548mm(H) Type D: 310mm(W) x 504mm(D) x 462mm(H)	360mm(W) x 530mm(D) x 565mm(H)
Weight	Type F: 21 kg with the digital camera Type D: 21 kg	26 kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2005

Kowa Company, Ltd.
c/o Tamas Borsai
Division Manager, Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Rd.
Newton, CT 06470

Re: K053026
Trade/Device Name: Kowa nonmyd 7 (type F) & nonmyd α-D (type D) Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: October 25, 2005
Received: October 27, 2005

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if know): K053026

Device Name: KOWA nonmyd 7 and KOWA nonmyd α-D

Indications for Use:

The KOWA nonmyd series, non-mydriatic fundus camera, are intended for use with retina image capturing. The retina image can be stored to an external hard disk drive or transferred in other formats through memory card or serial interface depending on the output interface available for each device.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use [redacted] (21 CFR 801 Subpart C)

(PLEASE DO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)